

# Implementation and Validation of a Novel Noninvasive blood Pressure Measurement Algorithm Based on Oscillometric Method with Obtaining International Hypertension Standards

## Abstract

**Background:** One of the most prevalent methods in noninvasive blood pressure (BP) measurement with cuff is oscillometric, which has two different types of deflation, including linear and step deflation. With this approach, in addition to designing a novel algorithm by the step deflation method, a sample of its module was constructed and validated during clinical tests in different hospitals. **Method:** In this study, by controlling the valve, the pressure would be deflated through optimized steps. By real-time processing on the obtained signal from the pressure sensor, pulses in each step would be extracted. After that, in offline mode, mean arterial pressure is estimated based on curve fitting. **Result:** A BP simulator, various modules, and an auditory method were used to validate the algorithm and its results. During clinical tests, 80 people (men and women), 11 dialysis patients, and 69 non-dialysis (healthy or with other diseases) in the age range of 17–85 years participated. **Conclusion:** The obtained results compared with the BP simulator are in the standard range according to the international medical standards of the British Hypertension Society (BHS) and the US Association for the Advancement of Medical Instrumentation (AAMI), which are the global standard of comparison in this field.

**Keywords:** Blood pressure, cuff, noninvasive measurement, oscillometric

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## Introduction

Blood pressure (BP) is one of our body's most important vital signs, so precise BP measurement is critical.<sup>[1]</sup> According to the latest published statistics, over one billion people around the world suffer from high BP. High BP is the third cause of death worldwide, and the number of deaths is expected to rise sharply in upcoming decades due to this problem. High BP also generates and intensifies cardiovascular diseases.<sup>[2]</sup> Accurate BP measurement is a vital prediction for evaluating health conditions. Hence, it is an important decision-maker in the detection of cardiovascular patients.<sup>[3]</sup> The Seventh Report of the National Committee on Prevention, Detection, Evaluation, and Treatment of High BP recommends that prevention and management of hypertension are major public health challenges; therefore, healthy people of all ages, in addition to patients,

should have measured their BP regularly and accurately. That is why even the smallest differences are important in this measurement.<sup>[2]</sup> Indeed, the methods of determining BP have been improved with technological progress during recent years. However, it should be noted that despite technological advancements, in some cases, it is still difficult for medical professionals to measure BP noninvasive with high accuracy.<sup>[4]</sup> Still, there is uncertainty because BP continuously varies, and it is directly linked by physiological variation, diseases, stress, food, and many other factors.<sup>[5]</sup>

Among invasive and noninvasive measurement methods, noninvasive methods are used more to measure BP, although they are less accurate than invasive methods.<sup>[1]</sup> Auditory and oscillometric methods are the most well-known and common noninvasive methods.<sup>[4]</sup>

Due to its high speed and efficiency, the oscillometric method has been widely

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used in most automatic BP devices.<sup>[6]</sup> This method is implemented based on extracted pulses from arterial pressure.<sup>[7]</sup> The oscillometric process requires an inflatable cuff, a processor unit (microcontroller unit [MCU]), and a pressure transducer.

The cuff is usually placed around the upper arm to block the brachial artery. The pressure sensor measures the cuff pressure during the period of inflating and deflating. There are two ways to deflate cuff pressure in the oscillometric method: step deflation and linear deflation. Although the linear method has a high-speed performance, it would be easily affected by noise and motion artifacts.<sup>[8]</sup>

Various oscillometric algorithms are based on analyzing oscillometric waveform envelope. They may be peak-peak or baseline to peak and maximum slope,<sup>[9]</sup> but their accuracy is still uncertain or, in some cases are unreliable. In the step deflation method, detection of two pulses in each step is required during deflation, which is time-consuming but has high accuracy at the same time. Extensive research has shown that the maximum pressure obtained is related to mean arterial pressure (MAP), and accurate MAP estimation is vital for precise measurement.<sup>[10,11]</sup> That is why in this study, an attempt has been made to keep the advantages of the step deflation method and make it faster by minimizing the number of steps. Hence, to improve the accuracy of the BP measurement algorithm, a more reliable curve fitting to estimate MAP, systolic BP (SBP), and diastolic BP (DBP) is used.

## Methods

The hardware that is implemented to measure noninvasive BP (NIBP) with a cuff is shown in the block diagram in Figure 1a, and the designed hardware is shown in Figure 1b.

In this method, by wrapping the cuff around the arm, the brachial artery would be blocked. The cuff pressure is measured by using the pressure sensor. A pressure sensor must be able to measure from 0 to 300 mmHg. Hence, the MPX5050GP sensor was selected to measure 0–375 mmHg with 12 mV/mmHg sensitivity. The processor controls the speed of inflating the cuff by the pump and the deflating by the valve.

All of the fundamental signal processing is done by the microprocessor [Figure 2]. In this research, the LPC4088 processor has been used as a processor. This processor has 512 KB of memory, a maximum speed of 120 MHz, and a 12-bit analog-to-digital. The pressure signal  $x(n)$ ,  $n=1, 2, \dots, N$ ,  $N$  where is the number of total samples, is sampled by 12-bit A/D. The algorithm has two parts, the first part should be done in real-time, but for the second part, the time of performance does not matter. The online part should be finished in 5 mseconds. Thus, a time loop is needed for this purpose, which is designed as the following steps:

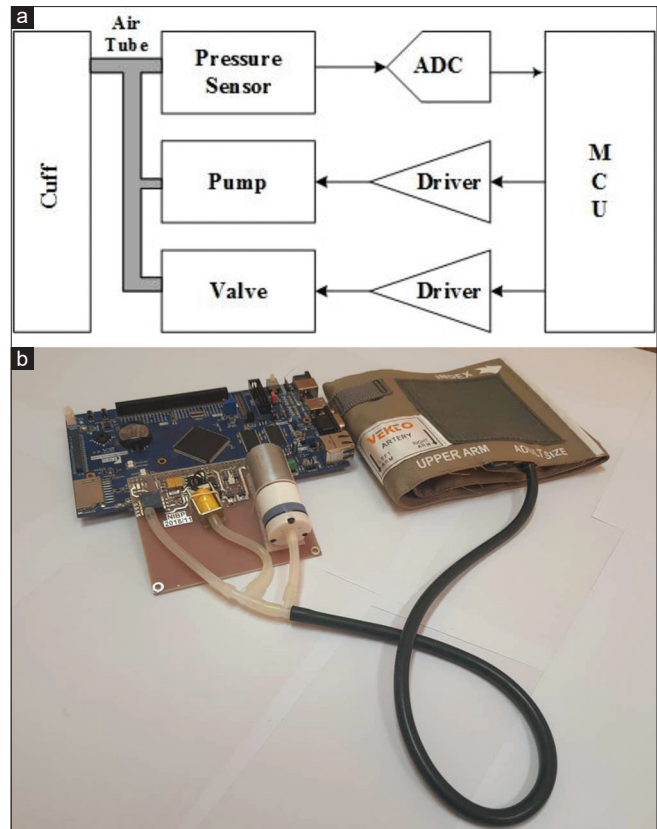


Figure 1: (a) Noninvasive blood pressure system block diagram. (b) Designed hardware for measuring noninvasive blood pressure

- Activate one of the MCU counters
- Adjust the counter in a way that can complete count lasts five milliseconds
- Activate the counter interrupt for completing each count
- Read one new sample of  $x(n)$  during interrupt.

In the first step, after sampling the  $x(n)$  to have a better signal for processing, a moving average filter with  $k$  sample is used as follows:

$$y(n) = \frac{1}{k} \sum_{j=1}^k x(n-j) \quad (1)$$

Now, it turns to measure the height of each pulse of  $y(n)$  signal ( $P1$  and  $P2$  in Figure 3). It is necessary to specify the beginning and end of each pulse and obtain its height for detecting two pulses in each step. For this purpose, a state machine with two states is designed.

As it can be seen in Figure 4, the first pulse occurs following an increasing slope after deflation in each step, and it is generally difficult to separate this slope from the desirable pulse in the signal, so at this moment, state zero is activated, and a derivation of  $y(n)$  is computed.

$$y'(n) = \frac{y(n+1) - y(n-1)}{2} \quad (2)$$

As soon as the first minimum is found in  $\dot{y}(n)$ , this point is named B1 and considered the pulse's beginning. Thus, the state zero finished, and state one begins. In the first state,

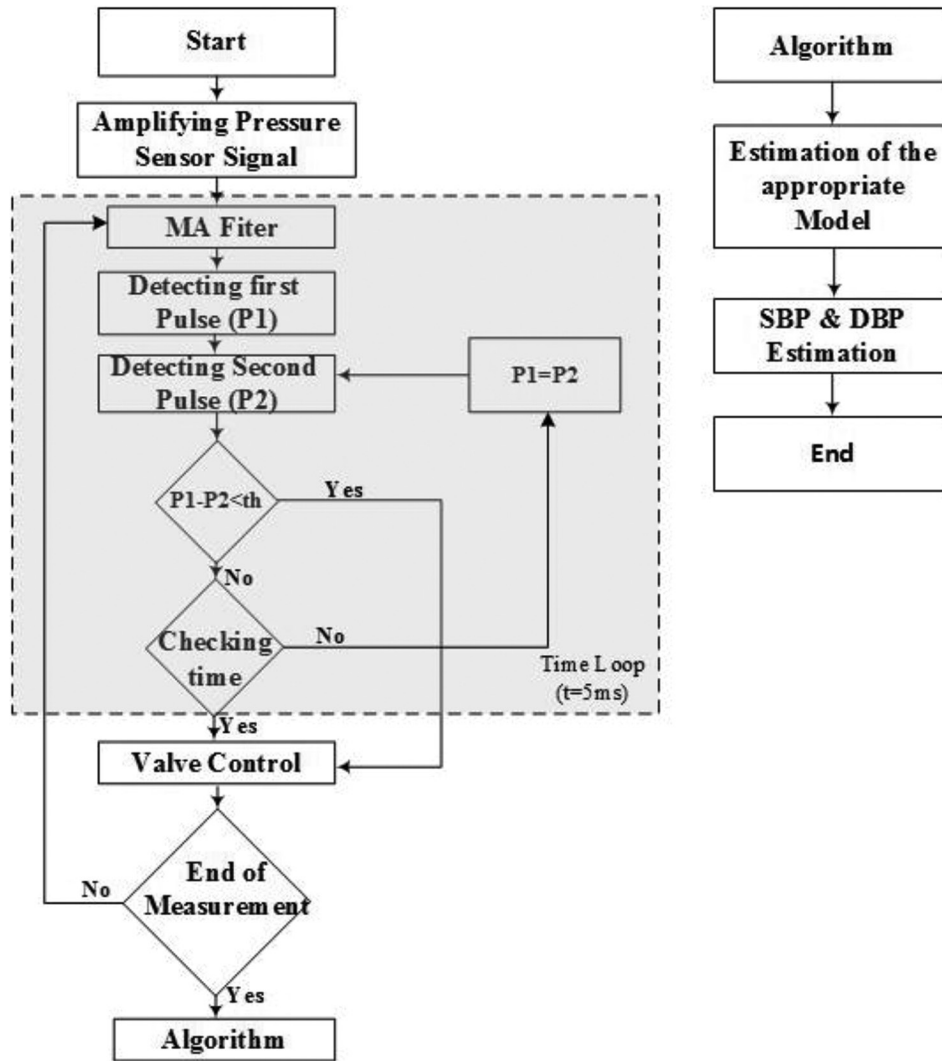


Figure 2: Diagram of noninvasive blood pressure measurement algorithm. This algorithm starts after cuff inflation. The left side is the way of measurement in each step and the right side is after the end of the measurement and obtaining SBP and DBP

samples related to the fastest incremental slope  $y(n)$  in are extracted [black points in Figure 3]. If  $p_n - p_{n-1} > Th_n$ , these two points are related to different slopes and  $p_{n-1}$  is E1 and  $p_n$  is B2 in Figure 4. So  $PI = y(E1) - y(B1)$  and this process continues until the end of each step to find two valid pulses or finish the step's time.

Therefore, the beginning and end of these positive slopes can be the maximum and minimum of desired pulses, and the height of the pulse can be estimated based on this information. In general, the minimum and maximum values are within 200 msonds. The systolic period occurs during this time. The height of each pulse is different, and it is between 0.4 and 4 mmHg. When the algorithm is searching for the fastest climbing point, the threshold is set based on the maximum slope. It means that the threshold can be set based on the morphology of the pressure signal during step deflation. Pulse morphology analysis is studying the shape of oscillometric pulses.<sup>[9]</sup> By setting this threshold,

it would be easier to detect two valid pulses in each step. Furthermore, it can prevent incorrect measurements because it is possible to face noises or obtain the wrong slope for finding pulses. Hence, with estimating the exact threshold, it will not happen. For finding the best threshold, the height of each sample is measured in comparison to its previous sample. Finally, a positive slope algorithm is designed to find two peaks in each step with appropriate accuracy and speed in the practical test.

### Valve control

In the oscillometric method, it is essential to control the valve and adjust the deflation time. There are some factors for controlling the pressure of each step, including opening valve time, opening valve position, and the cuff pressure at that step. To control the valve, the opening time parameter is used because the flow-opening feature is different even in two valves with the same model. After adjusting the desired pressure difference (in this case,

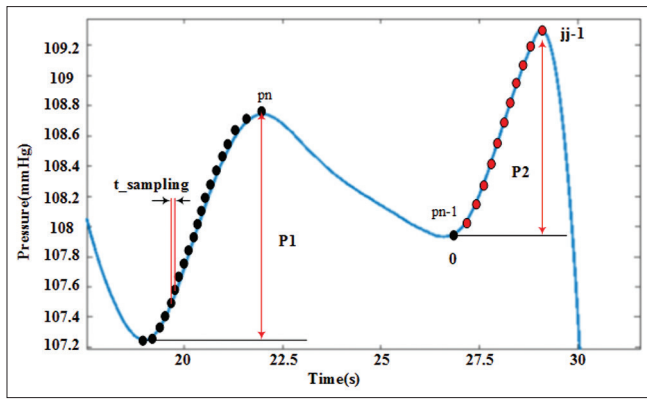


Figure 3: Finding best threshold for measuring height of each sample and true pulses in an accurate and ideal positive slope based on pulse morphology

5 mmHg), the pressure difference between the steps is controlled. If the pressure value is too small (<4 mmHg), the opening time should be increased, and if the value is too large (>6 mmHg), the opening time should be reduced. The pressure difference can be obtained by repeating the measurement. This algorithm has also been successful for different sizes and types of cuffs.

### Estimation of systolic and diastolic blood pressure

When the deflation is over, it means that the artery is fully open, and blood is flowing normally. Hence, the measurement phase ends [Figure 5]. Motion artifacts are sources of inaccuracy, and they can be produced by arm motion, muscle tremor, shaking, or any external vibration.<sup>[12]</sup> The proposed method uses a lower number of deflation steps than similar equipment to decrease the time of measurement. In addition, it does not take into account all the available detected pulses, and some of them are removed to increase accuracy. Initially, if the pulse is larger than 120% (or <80%) of the previous pulse, that pulse is removed because it can be a noise or motion artifact (another way to eliminate noises). After removing outliers, effective features would be extracted.<sup>[5]</sup> Finally, data as Figure 5 will be achieved. At this stage, the best model is estimated by solving the optimization problem with the objective function (equation 3).

$$\min_x \|F(x)\|_2^2 = \min_x \left( \sum_i F_i^2(x) \right) \quad (3)$$

where  $F(x)$  is the suitable model that is expected to be the most accurate envelope of pulses, in this study, three different  $F(x)$  curves fitting with different are designed in algorithm to have a more precise measurement:

$$F(x) = ax + b$$

$$F(x) = ax^2 + bx + c \quad (4)$$

$$F(x) = ax^3 + bx^2 + cx + d$$

where  $a, b, c,$  and  $d$  are the unknown parameters, and they estimated through the optimization problem.

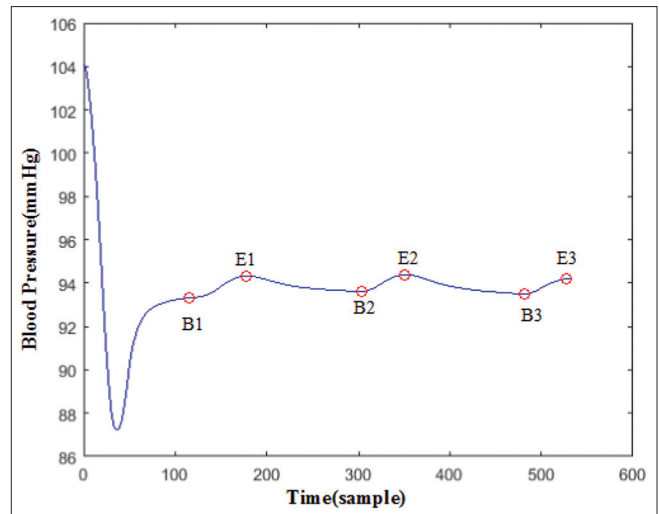


Figure 4: The beginning and end of each positive slope are marked with a red circle, which can be used to obtain the height of each pulse

The MAP would be the maximum of the fitted curve. Furthermore, SBP and DBP can be estimated using the ratios in Table 1, as shown in Figures 6-8.<sup>[13]</sup>

### Result and Validation

To validate the algorithm, the first step is using CAS-ND module data. For the beginning, the pressure data of CAS-ND should be recorded. Hence, with getting help from hardware and software that are shown in Figure 9, data were recorded and in excel format were saved. As it is evident in Figure 9 pressure signal is sampled by ADS1011 with 16 bit accuracy. For controlling and data transferring, Labview as software and LPC1768 as hardware are used. Then, the corresponding systolic and diastolic pressure of recorded data was saved. Finally, the proposed algorithm is implemented on these data and compared with CAS-ND results, as shown in Figure 10. The final validation step is using a BP simulator, an auditory method with two specialists (a doctor and a nurse).

Figures 11-16 show the Bland and Altman plot of the result. “1<sup>st</sup>\_O,” “2<sup>nd</sup>\_O,” and “3<sup>rd</sup>\_O” mean the results of suggested methods, and “Ref” means the auditory method with two specialists (a doctor and a nurse). These figures give information about the difference between the reference method and the proposed method. In addition, the time of measurement improved by about 30%.

Table 2 shows that quadratic and cubic methods have the best performance based on international standards during the validation module compared to auditory measurement.

Hypertension is commonly accompanied by Chronic Kidney Disease (CKD) and CKD progression. Based on this fact, numerous observational studies and clinical practice guidelines were a strong reason to establish a group of patients for our test among CKD patients because it is reported that CKD patients are considered a

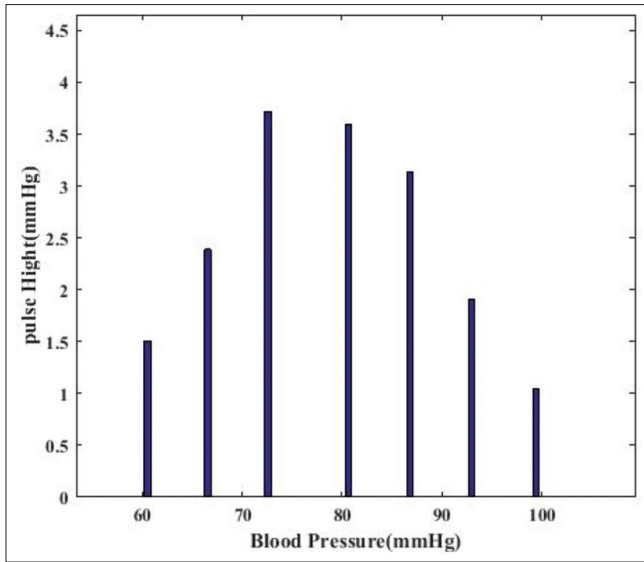


Figure 5: The size of the pulses obtained at each stage of the blood pressure measurement

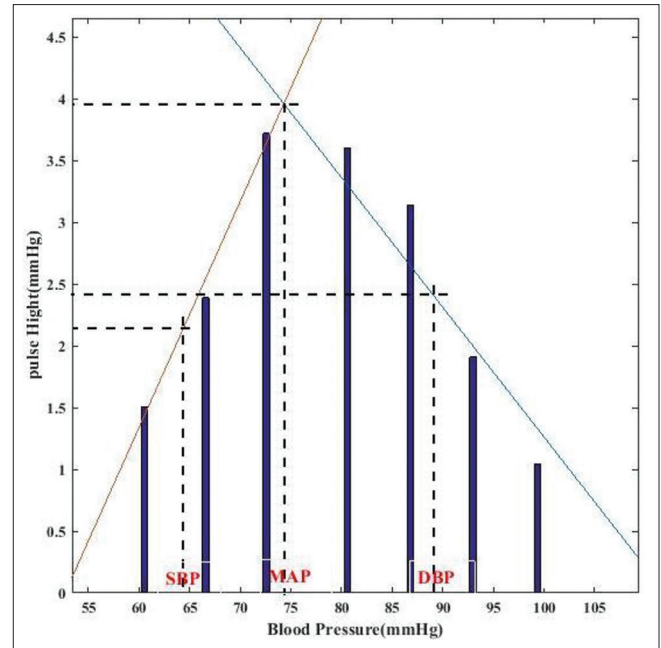


Figure 6: Fitting the linear curve to the obtained data from the peaks

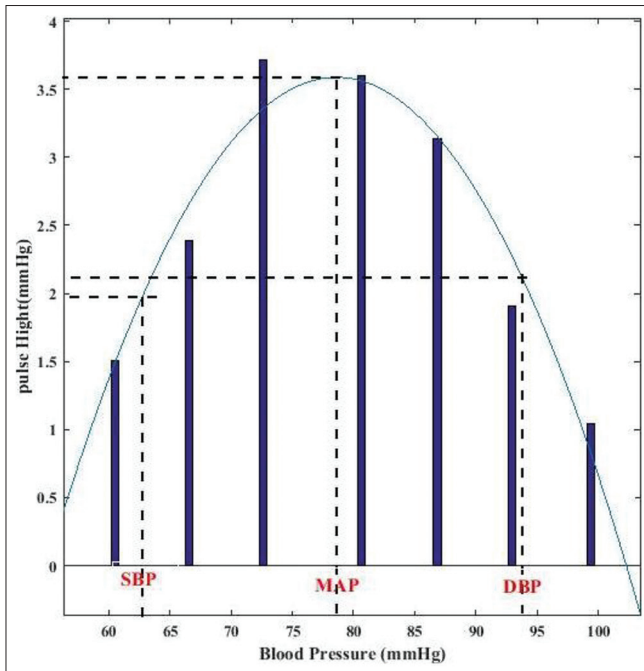


Figure 7: Fitting the quadratic curve to the obtained data from the peaks

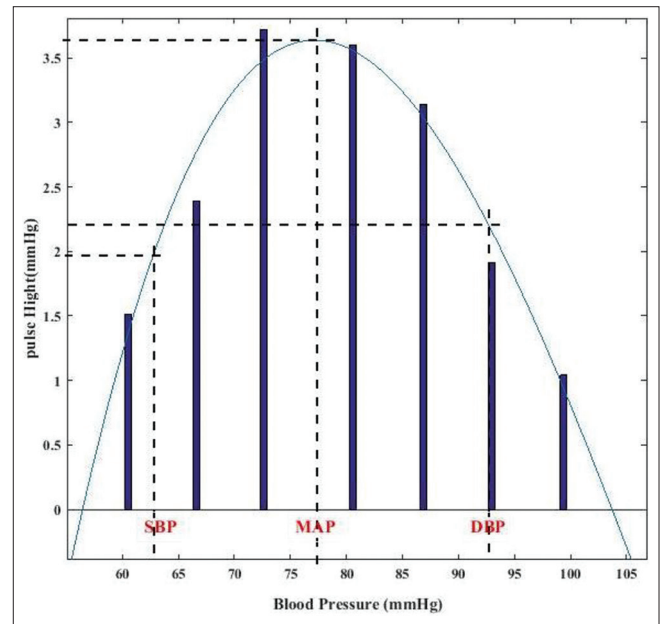


Figure 8: Fitting the cubic curve to the obtained data from the peaks

difficult group for BP measurements due to fluctuations in BP during dialysis.<sup>[14]</sup> It is necessary to mention that there is no difference in the measurement method, and it is just considered a challenge for testing the algorithm on different types of patients. Data collection and clinical tests were performed on 80 people (men and women), 11 dialysis patients, and 69 nondialysis patients (healthy or with other diseases) in the age range of 17–85 years old. BP was measured twice for each person, and in total, 160 measurements were obtained. The results of these tests were compared in a statistical analysis paired *t*-test. There was no significant difference between the measurements

Table 1: Systolic and diastolic coefficient

MAP	SBP coefficient	DBP coefficient
Over 165	0.38	0.60
165~116	0.46	0.58
115~95	0.57	0.62
94~77	0.55	0.6
76~60	0.65	0.68
59~40	0.65	0.65

MAP - Mean arterial pressure; SBP - Systolic blood pressure; DBP - Diastolic blood pressure

of the designed module and the auditory measurements by the physician and the nurse. The mean and standard

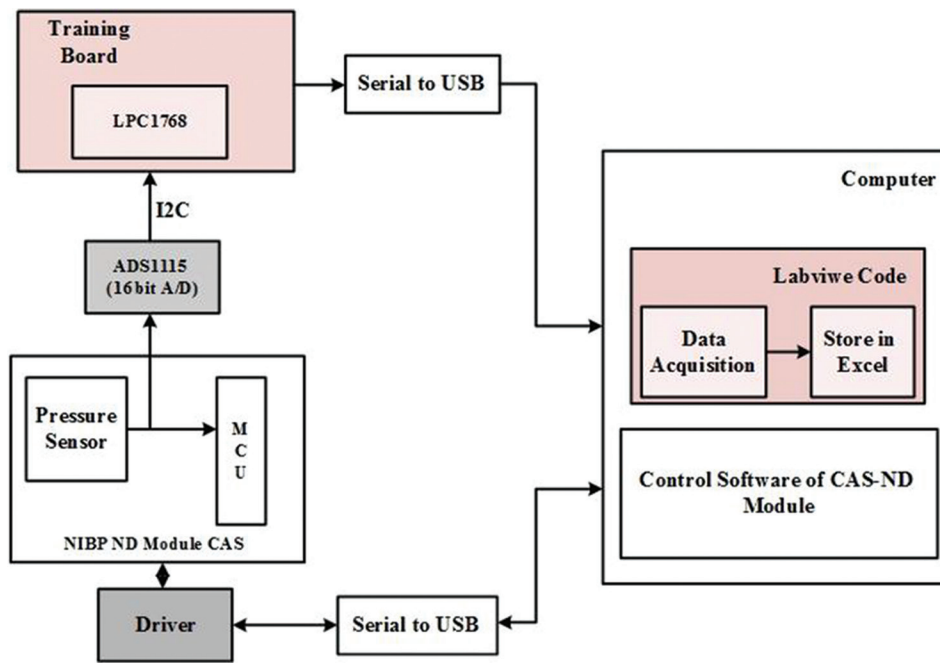


Figure 9: Data collection

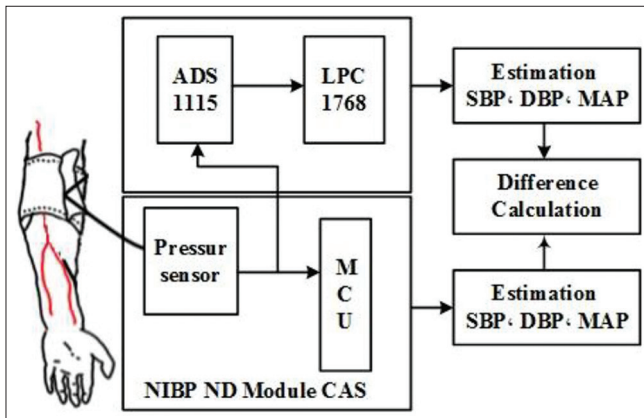


Figure 10: Blood pressure measurement method to validate the proposed algorithm

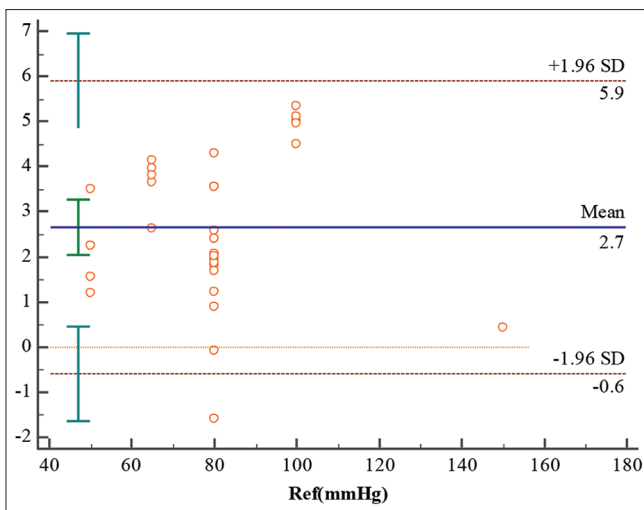


Figure 11: Bland-Altman for diastolic pressure with linear model estimation, 100% was considered within 5 mmHg of difference

**Table 2: Difference of mean and standard deviation of the proposed method with blood pressure auditory based on international standards (British Hypertension Society, advancement of medical instruments)**

Blood Pressure Values Mean±SD (mmHg)			
Blood Pressure Values	Linear	Quadratic	Cubic
SBP	5.1±8.53	2.6±4.4	2.4±4.25
DBP	2.76±1.63	2.59±5.36	3.53±7.12

SBP - Systolic blood pressure; DBP - Diastolic blood pressure; SD - Standard deviation

deviation of linear, quadratic, and cubic models for checking out international standards are shown in Table 2 and Figures 11-16. The standards are the Medical Standards of the British Hypertensive Society (BHS) and the American Association for the Advancement of Medical Instruments (AAMI), which are the global standards for comparison. The criterion for assessing the difference between the estimated and obtained BP in the BHS standard is divided into three parts: according to this standard, 60%, 85%, and 95% of the estimated cases should have differences <5%, 10%, and 15% mmHg, respectively. According to the latest version of the AAMI standard, with 85 people in the age range of 12–80 years (men and women), the BP monitor should have a mean error of <5 mmHg and a standard deviation of <8 mmHg. Patients, infants, and pregnant women have particular conditions that are needed to be examined in more detail. The reported numbers may vary according to the version of these standards.<sup>[15]</sup>

Other aspects of validity and reliability of this noninvasive method could be considered as the effect of patient's clothing in terms of thickness, and it can be investigated.<sup>[16]</sup>

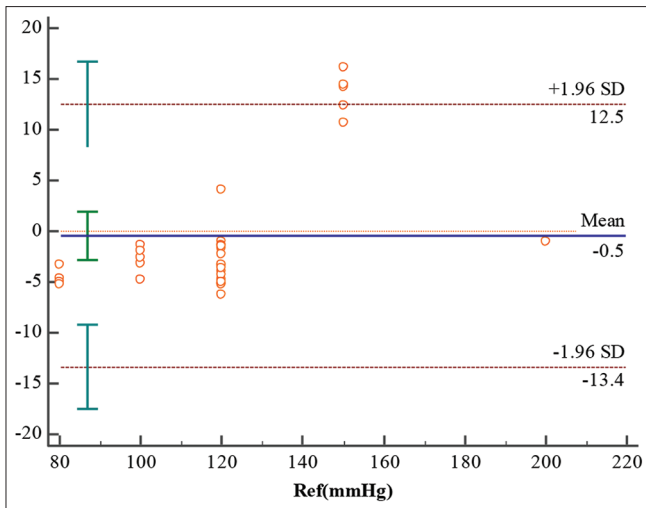


Figure 12: Bland-Altman for systolic pressure with linear model estimation, 80% was considered within 5 mmHg of difference

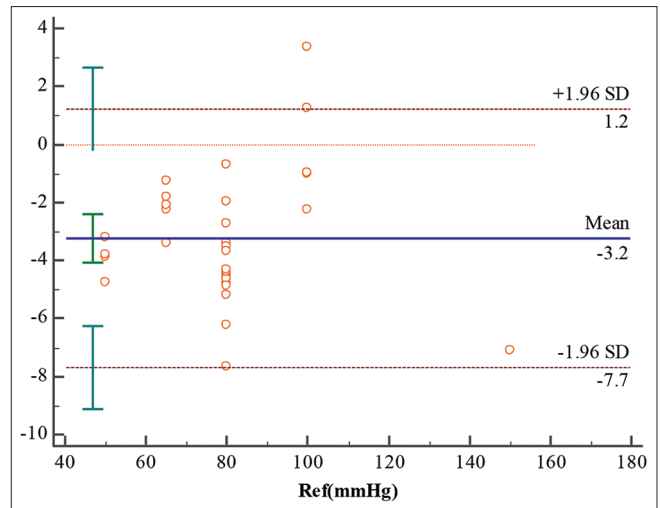


Figure 13: Bland-Altman for diastolic pressure with cubic model estimation, 93.5% was considered within 5 mmHg of difference

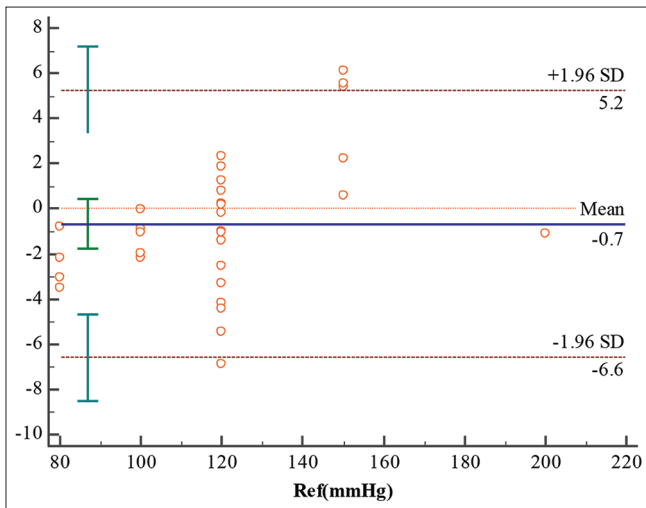


Figure 14: Bland-Altman for systolic pressure with cubic model estimation, 93.5% was considered within 5 mmHg of difference

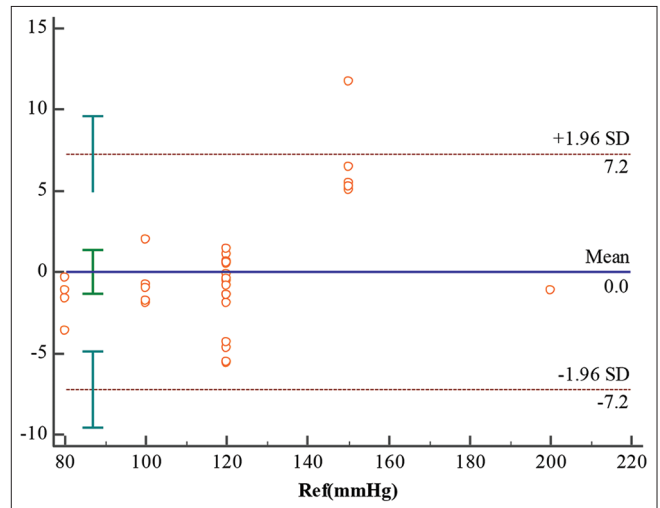


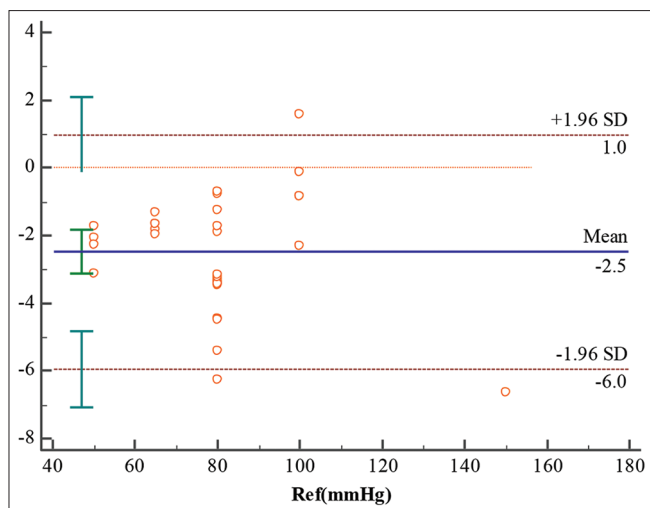
Figure 15: Bland-Altman for diastolic pressure with quadratic model estimation, 90.3% was considered within 5mmHg of difference

Furthermore, for continuing this project with this device and this algorithm, analyzing the algorithm's performance among cardiac patients could be a good challenge because it is reported that among cardiac patients, in comparison to the invasive method, other algorithms indicate different and sometimes unreliable results.<sup>[17]</sup>

## Conclusion

In this study, a novel method for determining BP based on oscillometric method and step deflation was represented by detecting two pulses in each step and curve fitting. It is essential to know that when the algorithm needs to be implemented with higher accuracy, the difference of each step can be designed shorter (2–3 mmHg), but it should be noted that the measurement time would be longer. Furthermore, it is vital to avoid motion artifacts and any noise as much as possible to increase accuracy. By detecting two pulses in each step with setting a threshold

and using the novel positive slope algorithm, a faster measurement could be possible. Moreover, curve fitting can help to have a more accurate measurement. Removing outliers before curve fitting can also play a key role in eliminating motion artifacts. Furthermore, analyzing the performance of algorithms among cardiac patients could be a good challenge because it is reported that among cardiac patients, in comparison to the invasive method, other algorithms indicate different and sometimes unreliable results. Furthermore, the effect of the patient's clothing in terms of thickness can be investigated. According to the possibility of required repetitions, the obtained results from the BP simulator for all linear, quadratic, and cubic fitting methods can achieve medical standards of the British Hypertension Association (BHS) and the American Medical Advancement Association (AAMI). Validation of the algorithm with hardware compared to the results of other modules in hospitals during clinical tests did not meet any



**Figure 16: Bland-Altman for systolic pressure with quadratic model estimation, 93.5% was considered within 5 mmHg of difference**

of the BHS and AAMI standards. Because, in clinical tests, it was not possible to repeat the measurements according to laboratory conditions and international standards, but the results of the NIBP module were not significantly different from the result of the physician by auditory method (<5 mmHg). Finally, the NIBP measurement system based on the oscillometric method can be implemented by designing this novel algorithm with more accurate and faster performance.

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### Conflicts of interest

There are no conflicts of interest.

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